

AMENDED CLAIMS

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AMENDED CLAIMS UNDER ART. 19

1. Composition comprising a mixture of
Diterpenic, Labdanes obtained from an plant *Andrographis*
5 *paniculata* dried extract, whose general formulae are:

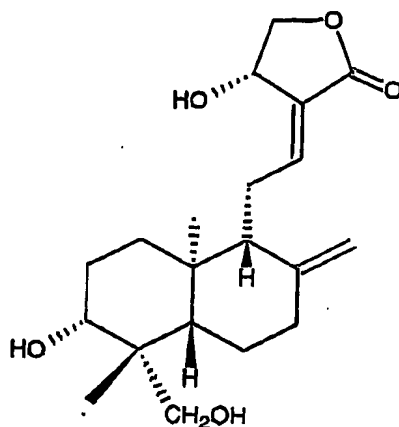
$C_{20}H_{30}O_5$ Andrographolide

$C_{20}H_{30}O_4$ 14-Deoxyandrographolide

$C_{26}H_{41}O_8$ Neoandrographolide

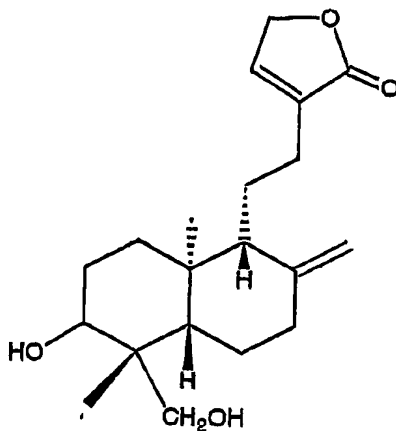
wherein each Diterpenic Labdane is present within the
10 mixture in an amount from about 20 to about 40% w/w of
Andrographolide, from about 3 to about 6% w/w of 14-
Deoxyandrographolide, and from about 0.2 to about 0.8 %
w/w of Neoandrographolide.

15 2. The composition, according to claim 1,
wherein the Andrographolide component is characterized by:
i.) general formula: $C_{20}H_{30}O_5$
ii.) molecular weight: 350.46
iii.) molecular nomenclature: 3-[2-[decahydro-6-hydroxy-5-
20 (hydroxymethyl)-5,8a-dimethyl-2-methylene-1-naphthalenyl]-
ethylidene]-dihydro-4-hydroxy-2(3h)-furanone,
iv.) molecular structure:



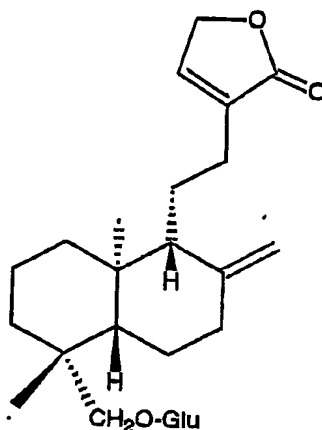
3. The composition, according to claim 1,
wherein the 14-Deoxyandrographolide component is
5 characterized by:

- i.) general formula: : C₂₀H₃₀O₄
- ii.) molecular weight: 336.46
- iii.) molecular nomenclature:
- iv.) molecular structure:



4. The composition, according to claim 1, wherein the Neoandrographolide component is characterized by:

- i.) general formula: $C_{26}H_{41}O_8$
- 5 ii.) molecular weight;
- iii.) molecular nomenclature:
- iv.) molecular structure:



10 5. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine, drug, pharmaceutical.

15 6. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating autoimmune diseases.

20 7. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating rheumatoid arthritis.

8. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating lupus exanthematous.

5 9. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating multiple sclerosis.

10 10. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for preventing and treating Alzheimer's disease.

15 11. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating asthma and allergies.

20 12. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating psoriasis.

25 13. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating the systemic dermatomyocytis.

14. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating osteoarthritis.

5 15. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating acquired immune deficiency syndrome (AIDS).

10 16. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating diabetes mellitus.

15 17. Use of the composition, according to claim 1, characterized in that it is useful for preparing a medicine suitable for treating the rejection in patients with tissue and organ transplants.

20 18. Pharmaceutical composition, characterized in that it comprises the composition according to claim 1, and a pharmaceutically acceptable carrier.

25 19. The pharmaceutical composition according to claim 18, wherein the diterpenic labdanes are present in an amount from about 25 to 35% w/w of Andrographolide, from about 4.5 to about 5.5% w/w of 14-Deoxyandrographolide, and from about 0.4 to about 0.8 % w/w of Neoandrographolide.

20. The pharmaceutical composition according to claim 19, wherein each diterpenic labdanes is present in an amount of 24.6% w/w of Andrographolide, 4.8% w/w of 14-Deoxyandrographolide, and 0.6% w/w of Neoandrographolide.

21. Composition, according to any one of claims 18-20, CHARACTERIZED in that it correspond to a pharmaceutical formulation in tablets form.

22. Pharmaceutical composition, according to claim 21, characterized in that it is orally administered contributing with the following doses for the following molecules:

- a) 1-5 mg andrographolide/kg per day
- b) 0.02-0.5 mg 14-deoxyandrographolide/kg per day
- c) 0.001-0.02 mg neoandrographolide/kg per day.

23. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating autoimmune diseases.

24. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating rheumatoid arthritis.

25. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating lupus exanthematous.

26. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating multiple sclerosis.

5 27. Use of the composition, according to claims 21 and 22, characterized in that it is useful for preventing and treating Alzheimer's disease.

28. Use of the composition, according to claims
10 21 and 22, characterized in that it is useful for treating asthma and allergies.

29. Use of the composition, according to claims
15 21 and 22, characterized in that it is useful for treating psoriasis.

30. Use of the composition, according to claims
21 and 22, characterized in that it is useful for treating systemic dermatomyocytis.

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31. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating osteoarthritis.

25 32. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating the acquired immune deficiency syndrome (AIDS).

33. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating diabetes mellitus.

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34. Use of the composition, according to claims 21 and 22, characterized in that it is useful for treating rejection of organs and tissues in transplanted patients.

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35. Pharmaceutical compositions, according to claim 18 CHARACTERIZED in that it can be enteral, parenteral, dermic, ocular, nasal, otic, rectal, vaginal, urethral, buccal, pharyngeal-tracheal-bronchial pharmaceutical forms, wherein the pharmaceutical composition comprises a dried extract containing a diterpenic Labdane mixture wherein each Diterpenic Labdane is present within the mixture in an amount from about 20 to about 40% w/w of Andrographolide, from about 3 to about 6% w/w of 14-Deoxyandrographolide, and from about 0.2 to about 0.8 % w/w of Neoandrographolide.

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36. The pharmaceutical compositions, according to claim 35, characterized in that the diterpenic labdanes are present in an amount from about 25 to 35% w/w of Andrographolide, from about 4.5 to about 5.5% w/w of 14-Deoxyandrographolide, and from about 0.4 to about 0.8 % w/w of Neoandrographolide.

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37. The pharmaceutical composition according to claim 36, wherein each diterpenic labdanes is present in an amount of 24.6% w/w of Andrographolide, 4.8% w/w of 14-Deoxyandrographolide, and 0.6% w/w of Neoandrographolide.

38. Pharmaceutical compositions, according to anyone of claims 35 to 37, characterized in that they are administered by the corresponding routes, in the following doses:

- a) 1-5 mg andrographolide/kg per day
- b) 0.02-0.5 mg 14-deoxyandrographolide/kg per day
- c) 0.001-0.02 mg neoandrographolide/kg per day.

39. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating autoimmune diseases.

40. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating rheumatoid arthritis.

41. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating exanthematous lupus.

42. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating multiple sclerosis.

5 43. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for preventing and treating Alzheimer's disease.

44 Use of the pharmaceutical composition,
10 according to claims 35 to 38, characterized in that it is useful for treating asthma and allergies.

45. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is
15 useful for treating psoriasis.

46. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating systemic dermatomyocytis.
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47. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating osteoarthritis.

25 48. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating acquired immune deficiency syndrome (AIDS).

49. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating diabetes mellitus.

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50. Use of the pharmaceutical composition, according to claims 35 to 38, characterized in that it is useful for treating the rejection of organs and tissues in transplanted patients.

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